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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/027,418

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EXAMINER

EREZO, DARWIN P

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/027,418	Applicant(s) PATEL ET AL.	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-13,32-39,43-48,62,69-72 and 74-76 is/are pending in the application.
- 4a) Of the above claim(s) 1-6,9-13 and 32-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,39,42,44-48,62,69 and 74-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/8/08 has been entered.
2. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

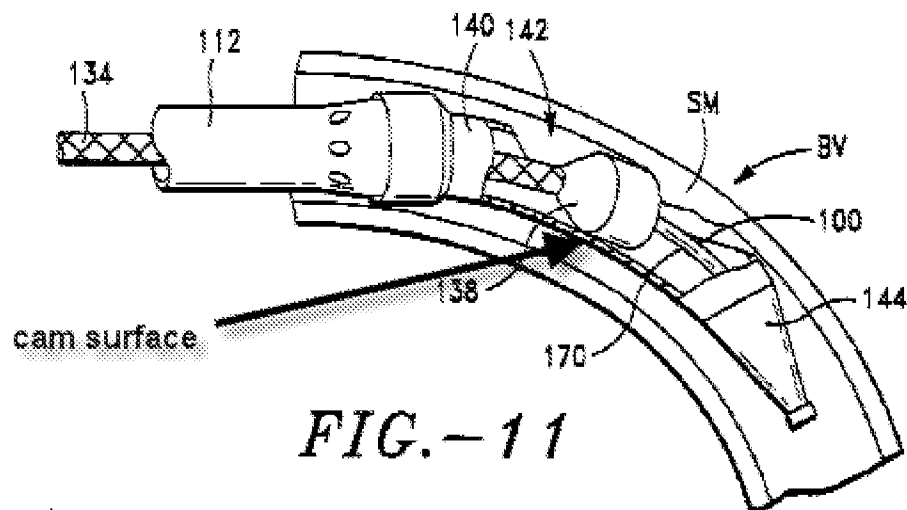
Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 39, 42, 44-46, 48, 62, 69-72 and 74-76 are rejected under 35 U.S.C. 103(a) as obvious over US 5,643,296 to Hundertmark et al. in view of US 5,053,044 to Mueller et al.

(claim 39) In Fig. 11, Hundertmark discloses a method of removing material (atherectomy) comprising the steps of: delivering a catheter having a tissue debulking device or cutter **138**; deflecting a distal portion of the catheter to a proximal portion of the catheter to expose the cutter, wherein the proximal movement of the catheter through a tortuous blood vessel causes the deflection against an inner cam surface of the catheter (see attached Fig. 11); and debulking the body lumen by rotating the cutter about an axis to expose the cutter through a cutting window **142**.



Hundertmark is silent with regards to the step of advancing the catheter in the body lumen to move the rotating tissue debulking device and cutting window through material in the body lumen during the deflecting step. However, the operation of the device shown in Fig. 11 clearly shows a device that is not secured to the region of stenosis since the tortuous passageway of the blood vessel will urge the distal end of the catheter to deflect and cause the cutter to be exposed from the cutting windows. As shown in the figure, the inflatable portion of the catheter is not inflated. Therefore, the device of Hundertmark is capable of being moved through the body lumen of the blood vessel during the cutting process.

Mueller discloses a similar method/device as Hundertmark, wherein the method comprises the steps of advancing the device through a patient's vascular system to the blood flow lumen BV; forcing the opening toward a wall of the site where material is to be removed; activating the cutting element 46 to extend the blade out of opening; and

moving the cutting element and the opening, together, in a forward direction after the forcing step so that material in the blood flow lumen is cut by the blade 46 (see col. 1, lines 59-68).

Therefore, one of ordinary skill in the art at the time the invention was made to modify the methodology of Hundertmark to include the method step of Mueller because it has been held that the use of a known technique (the step taught by Mueller) to improve similar devices (the device of Hundertmark) in the same way will yield predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007). Furthermore, it would be obvious to advance the device along the blood vessel while cutting if the region of stenosis is bigger than the cutting window.

It is also noted that the inner surface of the catheter adjacent the location of the cutter acts as a cam surface when the distal end of the catheter is deflected, as shown in Fig. 11.

As to claim 42, Hundertmark teaches the cutter rotating about the longitudinal axis of the catheter (Fig. 12).

As to claim 44, Hundertmark teaches a hollow nose cone **144** for packing or storing the severed material.

As to claims 45 and 48, Hundertmark teaches the deflection of the catheter occurring when the catheter is in a curved region of a blood vessel and the cutter is being urged against the tissue to be cut (moving the cutter from one position to the next position can occur simultaneously with the movement of the catheter).

As to claim 46, Hundertmark discloses a guidewire **146**.

As to claims 62, 69-72 and 74-76, Hundertmark discloses a method of debulking a body lumen comprising the steps of: providing a catheter having a rotating cutter **138**, a collection chamber **144**; a cutting window **142**; the cutter having a stored and exposed position (Fig. 10 or 1 and Fig. 11, respectively); wherein the cutter would be in the stored position prior to being placed within the body lumen; wherein the catheter has means for rotating the cutter (col. 7, lines 17-20); exposing the cutter (Fig. 11); advancing the catheter to remove occlusive material while rotating the cutter (inherent in the operation of an atherectomy device); wherein the window is a side opening in the catheter; and wherein the a drive shaft is connected to spline **130**, which is then connected to a motor drive unit. It is also noted that the device is fully capable of maintaining its orientation if moved along a constant curved body lumen, as seen in Fig. 11. The modification to include the step of advancing the device through the occlusive material while the cutter is exposed is provided in the rejections to claim 39.

5. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hundertmark in view of Mueller et al., and in further view of US 5,941,869 to Patterson et al.

The above combination of Hundertmark/Mueller teaches a method for cutting tissues within the vascular system of a patient but is silent with regards to using a cutter for removing tissues within a stent. However, Patterson teaches a method and device for cutting tissues, wherein a cutter is used to remove tissues within a stent (see Title and abstract). The device used in the method of Patterson is similar to the device used in the method of Hundertmark. Therefore, it would have been obvious to one of

Art Unit: 3773

ordinary skill in the art at the time the invention was made to use the device of Hundertmark to remove tissues within a stent since it is well known in the art to use cutters to remove stenotic materials from stents, as taught by Patterson. It is also noted that Hundertmark discloses using a cutter to remove tissue within a blood vessel, and that stents are normally located within blood vessels.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 39, 42, 44-48, 62, 69-72 and 74-76 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-24 of copending Application No. 10/421979 and claims 1-15 of copending Application No. 10/288581. Although the conflicting claims are not identical, they are not patentably distinct from each other because each recite a method of

debulking a body lumen by providing a catheter with a cutter and exposing the cutting through a cutting window. The differences in the wordings of the claims are obvious to one of ordinary skill in the art.

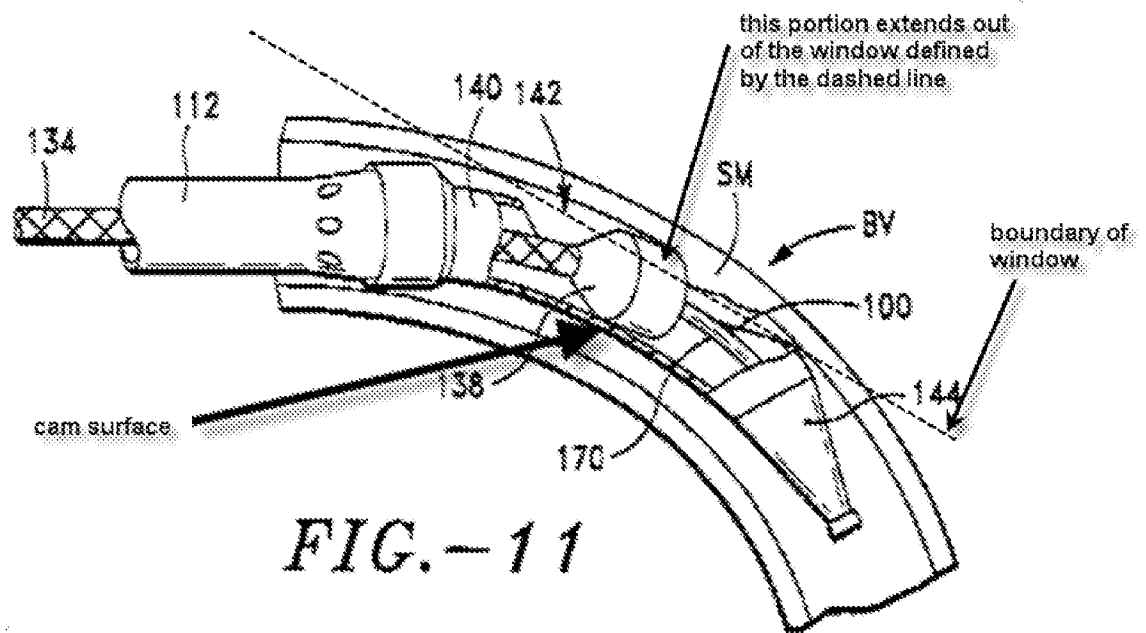
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

8. Applicant's arguments filed 9/8/08 have been fully considered but they are not persuasive.

The applicant's main argument is directed towards the examiner's interpretation of the Hundertmark reference. It was argued that the cutter 138 shown in Fig. 11 does not extend beyond the cutting window.

The examiner admits that Hundertmark discloses a shaft 170 that limits the movement of the cutter relative to the housing. However, the shaft does not completely prevent the cutter from extending beyond the cutting window of the housing. Hundertmark merely states that it keeps the cutter "generally within the housing". That is, the cutter bends along with the housing instead of maintaining a linear shape. However, as shown in the figure below, a portion of the cutter clearly extends outside the window/housing, which is the boundary defined by the dashed lines.



Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezzo/
Primary Examiner, Art Unit 3773